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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,539	04/04/2001	Howard Preissman	361722000201	9912

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FRANK P. BECKING
BOZICEVIC, FIELD & FRANCIS, LLP
200 MIDDLEFIELD ROAD
SUITE 200
MENLO PARK, CA 94025

EXAMINER
MILLER, CHERYL L

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/828,539	Applicant(s) PREISSMAN, HOWARD
	Examiner Cheryl Miller	Art Unit 3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-44 and 46-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-44 and 46-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Arguments

Applicant's arguments filed December 27, 2002 have been fully considered but they are not persuasive. In response to applicant's argument to the Ersek reference, Ersek does indeed disclose two different particle sizes within one composition, including smaller and larger particles within the ranges claimed (see col.3, lines 45-47; col.5, lines 64-68; col.6, lines 1-2), which may be used with soft or hard tissues, which are analogous arts (col.3, lines 50-60). In response to applicant's argument to the Draenert reference, Draenert discloses a composition used for the same purpose of the applicant, a filler implant material, and discloses particles of a small size, in the lower range that is claimed by the applicant (1-250um). Since Draenert's particles are disclosed as being the same size, if not smaller than the injectable particle size claimed by the applicant, Draenert's particle size is inherently injectable. In response to applicant's argument to the Cooke in view of Ersek rejection, the Ersek reference is used as a teaching for optimal particle size. Because Ersek's optimal particle size is identical to the particle size of the applicant and both inventions are used for the same purpose, implantation fillers, the rejection stands.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 40-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Ersek et al. (USPN 5,258,028, cited in previous office action). Ersek discloses a flowable matrix (31) and radiopaque particles (30), (col.3, lines 7-8, 15-18; col.10, lines 23-26) having a size between 350μ and 2200μ, 570μ and 2200μ, 450μ and 1600μ, or 570μ and 1150μ (col.5, lines 43-45), and further having smaller particles having a size between 120μ and 350μ (col.5, line 64-col.6, line 2).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 33-39 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Draenert et al. (USPN 6,080,801, cited by applicant in IDS) in view of Ersek et al. (USPN 5,258,028). Referring to claim 33, Draenert discloses a composition comprising a biocompatible matrix (col.3, lines 22-29), radiopaque particles, and a liquid contrast agent (liquid and/or solid contrast agents, col.3, lines 58-64). Draenert does not disclose however, particles having a size of 120μ to 2200μ. Ersek teaches radiopaque particles having an increased size of 120μ to 2200μ, in order to optimize the size for aiding in injection, and avoiding the adverse effects of smaller particles (col.3, line 60-col.4, line 44; col.6, lines 8-12). Because Ersek's particle sizes are injectable, Draenert's composition of even smaller particles is inherently injectable. It would have been obvious to one having ordinary skill in the art at the time the invention was made to

combine Draenert's composition including radiopaque particles, with Ersek's teaching of increased particle size, in order optimize size to aid in injection.

Referring to claim 34, Draenert discloses matrix and particles forming a slurry (admixture, col.2, line 50; col.4, lines 38-44).

Referring to claim 35, Draenert discloses a mixture of matrix and particles forming a hard tissue implant (col.1, lines 18-24).

Referring to claims 36-39, Ersek teaches particles having a size of between 350μ and 2200μ, 570μ and 2200μ, 450μ and 1600μ, or 570μ and 1150μ (col.5, lines 43-45) for the reasons above, and further having smaller particles having a size between 120μ and 350μ in order to provide variation in size to ease injection and to take into account normal variation from patient to patient so that the composition may be used with all patients in various locations (col.5, line 64-col.6, line 2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Draenert's composition having radiopaque particles, with Ersek's teaching of optimal particle size with particle variation, in order to provide smaller and larger particles in order to ease the injection and take into account patient and implant location variation, so that the composition may be used with all patients and at various tissue sites of all sizes.

5. Claims 47-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cooke et al. (USPN 5,336,699, cited by applicant in IDS) in view of Ersek et al. (USPN 5,258,028). Referring to claims 47 and 49-53, Cooke discloses an injectable composition (col.8, lines 28-31) comprising a hard tissue implant biocompatible matrix (col.2, lines 58-61) and radiopaque particles mixed within the matrix (col.1, lines 18-19). Cooke does not disclose however,

particles having a size between 120μ and 2200μ, 350μ and 2200μ, 450μ and 1600μ, 570μ and 1150μ, and additional particles having a size between 120μ and 350μ or up to 350μ. Ersek teaches radiopaque particles having a size between 120μ and 2200μ, 350μ and 2200μ, 450μ and 1600μ, 570μ and 1150μ, and additional particles having a size between 120μ and 350μ or up to 350μ in order to increase the size (optimizing), which in turn aids in injection (col.3, line 60-col.4, line 44; col.6, lines 8-12) and provides variation in size (smaller and larger particles) taking into account normal variation from patient to patient and implant location (col.5, line 64-col.6, line 2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the composition of Cooke including radiopaque tissue particles, with Ersek's particle size and size variation for tissue implants, in order optimize size, in turn aiding in injection, and to optimize the use from patient to patient, and tissue location to tissue location.

Referring to claim 48, Cooke discloses a matrix and particles forming a slurry (intermixed, col.8, lines 65-69; col.4, lines 55-60).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Cheryl Miller
March 7, 2003

BRUCE SNOW
PRIMARY EXAMINER